company announcement

Once-weekly and once-monthly Mim8 demonstrate superior reduction of treated bleeding episodes compared to on-demand and prior prophylaxis treatment in people with haemophilia A in the Frontier 2 trial

Bagsværd, Denmark, 13 May 2024 – Novo Nordisk today announced the headline results from the FRONTIER 2 trial, a pivotal phase 3a, 26-week open-label, randomised, controlled, multi-arm trial in 254 people. The trial investigated the efficacy and safety of once-weekly and once-monthly subcutaneous Mim8 versus no prophylaxis and versus prior coagulation factor prophylaxis treatment in people aged 12 years or older with haemophilia A with or without inhibitors.

The trial achieved its co-primary endpoints by demonstrating a statistically significant and superior reduction of treated bleeding episodes with both once-weekly and once-monthly Mim8 versus no prophylaxis treatment and prior coagulation factor prophylaxis treatment.

In people with no prior prophylaxis treatment, once-weekly and once-monthly Mim8 demonstrated superior reductions of 97% and 99% in treated bleeds, respectively, compared to those who received no prophylaxis treatment. In addition, 86% of people treated with once-weekly Mim8 and 95% of those treated with once-monthly Mim8 experienced zero treated bleeds, compared to 0% of those treated with no prophylaxis.

In the intra-patient analysis in people with prior coagulation factor prophylaxis, once-weekly and once-monthly Mim8 demonstrated superior reductions of 48% and 43% in treated bleeds, respectively, compared to prior coagulation factor prophylaxis (during run-in period of 26-52 weeks prior to initiation of Mim8 treatment). Additionally, 66% of people treated with once-weekly Mim8 and 65% of people treated with once-monthly Mim8 experienced zero treated bleeds.

In the trial, Mim8 appeared to have a safe and well-tolerated profile in line with previous trials. No deaths or thromboembolic events were reported in the trial.

“We are very pleased with the positive results from the FRONTIER 2 clinical trial. These data demonstrate the ability of Mim8 to prevent bleeding episodes effectively and safely in people with haemophilia A, regardless of their dosing frequency,” said Martin Holst Lange, executive vice president for Development at Novo Nordisk. “Given the differing needs of people living with

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haemophilia A, a convenient once-weekly or once-monthly dosing provides optionality and flexibility for people living with haemophilia A with or without inhibitors."

Contingent on regulatory interactions, Novo Nordisk aims to submit Mim8 for the first regulatory approval towards the end of 2024. Data from the phase 3 FRONTIER programme, including FRONTIER 2 will be disclosed at upcoming congresses and in publications in 2024 and 2025.

About Haemophilia

Haemophilia is a rare inherited bleeding disorder that impairs the body's ability to make blood clots, a process needed to stop bleeding. It is estimated to affect approximately 1,125,000 people worldwide, and haemophilia A is estimated to account for 80-85% of all haemophilia cases. Due to the nature of haemophilia being a rare x-linked recessive disorder, it often presents differently in males compared to females, with ~ 88% of people diagnosed with haemophilia worldwide being male. There are different types of haemophilia, which are characterised by the type of clotting factor protein that is defective or missing. Haemophilia A is caused by a missing or defective clotting Factor VIII (FVIII). Some people with haemophilia may also develop inhibitors, which are an immune system response to the clotting factors in replacement therapy that cause treatment to stop working. Currently, it is estimated that up to 30% of people living with haemophilia A have inhibitors.

About Mim8

Mim8 is a next-generation FVIIIa mimetic bispecific antibody delivering sustained haemostasis for once-weekly or once-monthly prophylaxis for people living with haemophilia A, with and without inhibitors. Administered subcutaneously, Mim8 bridges Factor IXa/X (FIXa/FX) together upon activation, thereby replacing missing FVIII, which effectively restores the body's thrombin generation capacity, helping blood to clot.

About the FRONTIER Programme

The FRONTIER clinical development programme investigates Mim8 as a preventative treatment for people with haemophilia A, with or without inhibitors. The phase 3 programme includes:

FRONTIER 2 – a 52-week efficacy and safety phase 3 trial, with a 26-52-week run-in period comparing once-weekly and once-monthly Mim8 versus no prophylaxis, and versus prior coagulation factor prophylaxis treatment prior to enrolment in people aged 12 years and over with haemophilia A, with or without inhibitors. Following the completion of the 26-week main phase of the trial, a 26-week extension phase is ongoing.

FRONTIER 3 – a 52-week safety and efficacy phase 3 trial in paediatric patients with haemophilia A, with or without inhibitors (1-11 years). People will receive once-weekly Mim8 during the first 26 weeks and may subsequently choose to receive once-monthly Mim8.

FRONTIER 4 – an open-label extension following participation in the FRONTIER phase 2 and phase 3 studies. The study allows the collection of long-term safety data.

FRONTIER 5 – a 26-week phase 3 trial investigating pharmacokinetics, pharmacodynamics and safety of switching from previous emizicumab to Mim8 in adults and adolescents with haemophilia A, with or without inhibitors.

About Novo Nordisk

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat serious chronic diseases, built upon our heritage in diabetes. We do so by pioneering scientific breakthroughs, expanding access to our medicines, and working to prevent and ultimately cure disease. Novo Nordisk employs about 66,000 people in 80 countries and markets its products in around 170 countries. Novo Nordisk's B shares are listed on Nasdaq Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit novonordisk.com, Facebook, Instagram, X, LinkedIn and YouTube.

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